

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



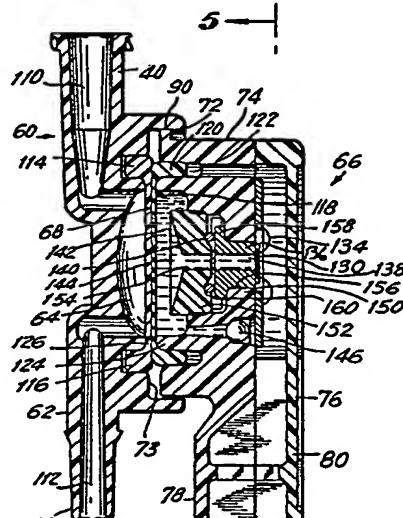
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (51) International Patent Classification 4 : G01L 9/06, A61B 5/02 | | A1 | (11) International Publication Number: WO 86/02446 (43) International Publication Date: 24 April 1986 (24.04.86) |
| (21) International Application Number: PCT/US85/01957 | | | (74) Agent: BERGER, Michael, J.; Amster, Rothstein & Engelberg, 90 Park Avenue, New York, NY 10016 (US). |
| (22) International Filing Date: 8 October 1985 (08.10.85) | | | |
| (31) Priority Application Numbers: | 660,455 764,665 | | (81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). |
| (32) Priority Dates: | 12 October 1984 (12.10.84) 9 August 1985 (09.08.85) | | |
| (33) Priority Country: | US | | Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> |
| (71) Applicant: AMETEK, INC. [US/US]; 410 Park Avenue, New York, NY 10022 (US). | | | |
| (72) Inventors: FRANK, Thomas, P. ; 481 Acorn Drive, Warminster, PA 18974 (US). PECHTER, David ; Rainbor View Farm, Rte. 29, River Road, Titusville, NJ 08560 (US). McFADDEN, Harold, Edward ; 1708 Bantry Drive, Dresher, PA 19025 (US). | | | |

(54) Title: PRESSURE TRANSDUCER

(57) Abstract

A transducer includes a fluid inlet port (152) formed with a passageway (154) permitting flow of fluid therethrough and a pedestal (136) having a base (158) and also formed with a passageway (138) permitting flow of fluid therethrough. A resilient seal (140) is disposed between the pedestal (136) and the fluid inlet port (152) so that fluid communication is permitted between the passageways of the port and pedestal. The relationship of the pedestal, port and seal is maintained by a support member (150) which is secured to the fluid inlet port and which contacts the base (158) of the pedestal so as to clamp the pedestal to the port with the seal (140) located therebetween. A pressure sensing element (130) is mounted to the pedestal so that the fluid contacts the sensing element and an indication of the pressure of the fluid is provided. The transducer is part of a pressure sensor used in a hemodynamic blood pressure monitoring system which includes a pressurized IV fluid which is conveyed to the blood stream of a patient, to sense the pressure of the pressurized fluid. A display is coupled to the pressure sensor for displaying the patient's blood pressure.



5

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | |
|---------------------------------|---------------------------------------------|-----------------------------|
| AT Austria | GA Gabon | MR Mauritania |
| AU Australia | GB United Kingdom | MW Malawi |
| BB Barbados | HU Hungary | NL Netherlands |
| BE Belgium | IT Italy | NO Norway |
| BG Bulgaria | JP Japan | RO Romania |
| BR Brazil | KP Democratic People's Republic of Korea | SD Sudan |
| CF Central African Republic | KR Republic of Korea | SE Sweden |
| CG Congo | LI Liechtenstein | SN Senegal |
| CH Switzerland | LK Sri Lanka | SU Soviet Union |
| CM Cameroon | LU Luxembourg | TD Chad |
| DE Germany, Federal Republic of | MC Monaco | TG Togo |
| DK Denmark | MG Madagascar | US United States of America |
| FI Finland | ML Mali | |

-1-

PRESSURE TRANSDUCER

This application is a continuation-in-part of application Serial No. 660,455 filed October 12, 1984.

The invention relates to pressure transducers and more particularly to a pressure transducer assembly in which the 5 pressure sensing element is isolated from stresses arising in other parts of the assembly. One application for such a pressure transducer is in a system for measuring blood pressure and in particular a hemodynamic blood pressure measuring system which can be used to continuously monitor the blood 10 pressure of a patient.

Presently, the high volume manufacture of pressure transducers includes the use of semi-conductor chips, each formed with a diaphragm having piezoresistive strain sensors. The strain sensors are connected in a circuit to measure the 15 diaphragm deflection due to pressure differential across the diaphragm caused by a fluid to be measured. A major problem associated with transducers employing these semi-conductor sensor chips is mounting the chip in the transducer housing so that the chip is isolated from stresses arising in 20 the housing which would otherwise result in diaphragm deflection and false pressure readings.

In one form of prior art transducer, a silicon pressure sensing chip is rigidly affixed by use of epoxy to a metallic header which forms part of the housing. This construction 25 suffers from several distinct disadvantages. Specifically,

-2-

since the chip, the epoxy and the metallic header have different temperature coefficients of expansion, unwanted stresses are induced in the chip resulting in unstable and non-repeatable pressure readings. The ability of the metallic 5 header to flex also induces unwanted stresses in the chip and results in an undesirable higher volumetric displacement and a correspondingly low frequency response. In addition, since the epoxy connecting the chip to the metallic header is exposed to the pressurized fluid to be 10 measured, the transducer can only be used to measure fluid which is compatible with the epoxy. Finally, the curing of the epoxy is both time consuming and variable and therefore not well suited to an economical high volume manufacturing process.

15 U.S. Patent No. 4,295,117 shows a pressure sensor assembly formed of a housing of molded polyester material within which a silicon pressure sensing chip is mounted. The chip and the housing have different temperature coefficients of expansion, and the patent describes a mounting arrangement 20 which attempts to protect the chip from thermally induced and other stresses. Specifically, as described in the patent, a glass base is secured to the housing by a soft resilient adhesive, which (the patentee asserts) largely prevents stress transmission from the housing to the base. The base is 25 formed with a short pedestal on which a rectangular shaped glass die is bonded by a relatively soft epoxy to further inhibit stress transmission. The silicon chip is then bonded

-3-

to the opposite side of the glass die by anodic bonding, the principles of which are described in U.S. Patent No. 3,397,278.

While the arrangement described in U.S. Patent No. 4,295,117 may serve to isolate the sensing chip from stresses induced in other parts of the transducer, it requires the use of a rectangular glass die secured to the short pedestal of a glass base by the use of a soft epoxy. This is undesirable for several significant reasons. First, the soft epoxy and the resilient adhesive both come in contact with the pressure media and therefore the transducer can only be used to measure pressure media which is compatible with the epoxy. Second, the curing of the epoxy (as well as the soft adhesive connecting the base to the housing) is a time consuming and variable process which is not well suited to an economical high volume manufacturing process. Finally, the epoxy has a different thermal coefficient of expansion than the die which adversely affects the accuracy and repeatability of the output of the transducer assembly.

It is therefore an object of the present invention to provide a transducer in which the pressure sensing element is isolated from stresses arising from thermal expansion and flexing of the various parts of the transducer packaging.

Another object of the present invention is to provide a transducer which by virtue of its simple design and small number of parts, lends itself to economical high volume manufacturing processes and methods.

-4-

Still another object of the present invention is to provide a transducer which is compatible with a wide range of pressure medias and provides excellent corrosion resistance.

5 A further object of the present invention is to provide a transducer which provides accurate and repeatable pressure readings yet is relatively inexpensive in manufacture.

A still further object of the present invention is to provide a transducer in which no wire bonds or circuit 10 components are exposed to the pressure media.

An additional object of the present invention is to provide a transducer which achieves an extremely low volumetric displacement and a correspondingly high frequency response.

15 These and other objects and features of the invention are accomplished by a transducer which includes a fluid inlet port formed with a passageway permitting flow of fluid therethrough and a pedestal having a base and also formed with a passageway permitting flow of fluid therethrough. A resilient 20 seal is disposed between the pedestal and the fluid inlet port so that fluid communication is permitted between the passageways of the port and pedestal. The relationship of the pedestal, fluid inlet port and seal is maintained by a support member which is secured to the fluid inlet port and which 25 contacts the base of the pedestal so as to clamp the pedestal to the port with the seal located therebetween. A pressure sensing element is mounted to the pedestal so that the fluid

-5-

contacts the sensing element and an indication of the pressure of the fluid is provided. The clamping action of the support member against the base of the pedestal as well as the positioning of the resilient seal between the pedestal and 5 port serve to isolate the pressure sensing element from unwanted stresses arising in the transducer.

The above brief description as well as further objects, features and advantages of the present invention will be more fully understood by reference to the following 10 detailed description of the presently preferred, but nonetheless, illustrative embodiments in accordance with the present invention, when taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a representation of a hemodynamic blood 15 pressure monitoring system incorporating the transducer of the invention;

Fig. 2 is an isometric and exploded view of the pressure sensor of the invention and showing the dome and transducer portions prior to assembly;

20 Fig. 3 is a top plan view of the assembled pressure sensor of the invention;

Fig. 4 is a sectional view of the pressure sensor of the invention taken along line 4-4 of Fig. 3 and looking in the direction of the arrows;

25 Fig. 5 is a sectional view of the assembled pressure sensor of the invention taken along line 5-5 of Fig. 4 and looking in the direction of the arrows;

-6-

Fig. 6 is a bottom plan view of the assembled pressure transducer of the invention;

Fig. 7 is an exploded perspective view of an alternate form of pressure transducer;

5 Fig. 8 is a sectional elevation of the transducer of Fig. 7 with the cover removed.

Referring first to Fig. 1, the hemodynamic blood pressure monitoring system 10 includes an IV fluid 12, such as a saline solution, contained within pressure bag 14 which 10 is pressurized using bulb 16 to the required conventional pressure which is read on pressure gauge 18. Pressure bag 14 containing pressurized IV fluid 12 is hung on an IV pole 20. Appropriate and conventional tubing 22 and fluid metering devices 24a, 24b couple the pressurized IV fluid 12 from the 15 pressure bag 14 to one port 26 of a conventional continuous flush device 28. Coupled to a second port 30 of continuous fluid device 28 is additional tubing 32 leading to a catheter 34 in the artery of the arm 36 of a patient. IV fluid 12 is thus conveyed under pressure from pressurized bag 14 via tube 20 22, continuous flush device 28, tube 32 and catheter 34 into a patient's artery. The patient's blood pressure can therefore be monitored by monitoring the pressure of the pressurized IV fluid 12.

To this end, a pressure sensor 38 is mounted on IV 25 pole 20. One fluid port 40 of pressure sensor 38 is coupled by tubing 42 to a third port 44 of continuous flush device 28. A second fluid port 43 of pressure sensor 38 is closed by a

-7-

stopcock 45. Pressure sensor 38 also has an electric cable port 46 into which is coupled one end of an electric cable 48. The other end of electric cable 48 is connected to a blood pressure display 50 which has appropriate provision of digital 5 readout of the patient's blood pressure on display devices 52 and 54 and for making a continuous record of the patient's blood pressure on chart recorder 56.

Continuous flush device 28 is constructed to couple pressurized IV fluid 12 to pressure sensor 38 via port 40 and 10 tube 42, as is well known in the art. Pressure sensor 38 responds to the pressure of the pressurized IV fluid 12 which is directly related to the patient's blood pressure. Pressure sensor 38 converts the sensed pressure into electric signals which are coupled by cable 48 to blood pressure display 50. 15 In this way, the blood pressure of the patient is continuously displayed on display devices 52 and 54 and recorded on chart recorder 56.

One embodiment of the pressure sensor 38 will now be described in more detail. Referring to Figs. 2 through 6; 20 pressure sensor 38 includes a dome portion 60 having a generally ring-shaped dome housing 62 with a chamber 64 (Fig. 4) formed therein to which first port 40 and second port 42 are coupled to convey IV fluid 12 to chamber 64. Pressure sensor 38 also includes a transducer portion 66 containing 25 pressure responsive elements which respond to the pressure of IV fluid 12 and which will be described in detail below. A circular opening in the interior of dome housing 62 leading

-8-

to chamber 64 is closed by a first rubber diaphragm 68 which flexes in response to the pressure of IV fluid 12 in chamber 64. Dome housing 62 also is formed with diametrically opposed ears 70, 72 which extend from the plane of the front surface 5 of dome 60 downward toward rim 73 surrounding the outer edge of first rubber diaphragm 68 leaving a space between rim 73 and the bottom of ears 70, 72 used in joining dome 60 to transducer 66.

Transducer 66 includes a generally circular housing 10 portion 74 and a generally rectangular housing portion 76 which contains electric cable receiving port 46. Preferably, transducer 66 is formed in two sections, an upper housing section 78 and a lower housing section 80 secured to one another. Projecting outwardly from opposite sides of the 15 rear face of the circular portion 74 of upper housing 78 are a pair of flanges 82, 84 having slots 86, 88 respectively through which a strap (not shown) or other device is passed to secure pressure sensor 38 to IV pole 20. Projecting outwardly from the front face of circular portion 74 of lower 20 housing 80 is a flange formed with diametrically opposed cut portions 92, 94, a ramp portion 96, 96' and flat portion 98, 98' leading from the cut portions 92, 92' to stop tabs 100, 100'.

Ports 40 and 42 of dome 60 each have a passageway 25 110, 112 respectively leading from the respective ports to dome chamber 64. To hold first rubber diaphragm 68 in dome 60, diaphragm 68 is formed with a peripheral circular rim 114 which is received within circular slot 116 formed in dome

-9-

housing 62. When pressurized IV fluid 12 is coupled to port 40 and port 42 is closed, pressurized IV fluid fills chamber 64 and passageways 110 and 112 causing a force to be extended on first rubber diaphragm 64.

5 Transducer 66 includes a second circular rubber diaphragm 118 formed with a peripheral circular rim 120 which is received within circular slot 122 formed in the front face of the transducer 66 and cooperatively positioned with slot 116 in dome 60. As best seen in Fig. 4, when dome 60 and 10 transducer 66 are joined together (as described below) diaphragms 68 and 118 are in contact with one another so that any force exerted on diaphragm 68 by IV fluid 12 is transmitted to diaphragm 118. The particular construction of dome 60 and transducer 66 ensures that the diaphragms are clamped to- 15 gether in such a way that they are constrained from lateral motion or flow in response to pressure exerted on the dia- phragms by the pressurized fluid. Lateral restraint for the diaphragm is one of the important features of the invention since restraining the diaphragms from lateral movement in- 20 creases the accuracy of transmission of the forces on IV fluid 12 from diaphragm 68 to diaphragm 118. The diaphragms are laterally restrained by the cooperation of circular rim 124 formed on transducer 66 inboard of peripheral circular slot 122 and circular rim 126 formed on dome 60 inboard of 25 peripheral circular slot 116 which clamps the peripheries of diaphragms 68 and 118 between them to restrain diaphragms 68 and 118 against lateral motion.

-10-

Transducer 66 includes a silicon piezoresistive pressure sensing element 130 consisting of four pressure responsive elements preferably in the form of piezoresistors diffused into a silicon wafer of approximately 0.010 inches 5 thick using standard semiconductor processes. This silicon wafer is subjected to a preferential chemical etch that forms a thin silicon diaphragm within the thicker silicon substrate. This thin diaphragm is necessary to the proper operation of the piezoresistive pressure sensing element 130.

10 Aluminum metallization provides an aluminum substrate 132 on the unetched (active) side of the silicon diaphragm, which in turn provides a means of electrically connecting the diffused piezoresistors to an electronic compensation circuit (not shown) to standardize the output of the pressure responsive

15 elements and provide temperature compensation, as is well known in the art. Electrical connections between the substrate 132 and connection pads formed on the circuit are made by wirebonding, using aluminum or gold wire 134 as small as 0.001 inches in diameter, as is also well known in the art.

20 The silicon pressure sensing element 130 is bonded to a glass pedestal 136 to provide mechanical stability. The glass chosen has a coefficient of expansion similar to that of bulk silicon. A seal in the form of an O-ring 140 is seated against glass pedestal 136 and provides a sealed port leading 25 to the passive side of pressure sensing element 130 through a passageway 138 formed in pedestal 136. Activating the passive side of pressure sensing element 130, as described,

-11-

is preferred because using the passive side eliminates the need to resolve problems associated with placing electrical connections (e.g. aluminum substrate 132 and wirebonds 134) in the pressurizing media.

5 Low viscosity high dielectric oil fluid 142 fills the transducer chamber 144 between rubber diaphragm 118 and the passive side of the pressure sensing element 130. The high dielectric oil 142 serves to hydraulically transmit the pressure applied to rubber diaphragm 68 to the passive side
10 of pressure sensing element 130 and aids in electrical isolation of pressure sensing element 130 from the pressurized IV fluid 12. The oil is placed into chamber 144 in transducer 66 under vacuum and then trapped by a stainless steel ball 146 which causes pressure on oil 142 to bow
15 diaphragm 118 outward slightly thus ensuring good mechanical contact between the diaphragms 68 and 118.

Pedestal 136 is retained in the upper housing section 78 of the transducer 66 between a support member 150, which is formed as part of section 78, and an oil inlet port 152 which includes a passageway 154 to permit fluid flow therethrough. Specifically, the support member 150 is formed with a passage 156 in which the pedestal 136 is placed. The pedestal 136, however, is formed with a cylindrical base portion 158 which contacts the lower surface of support member 150 and therefore does not move through the passage 156. The O-ring 140 is located between the lower surface of the base 158 of the pedestal 136 and a recess 160 formed in

-12-

the port 152. During assembly of the transducer 66, the support member 150 is secured to the port 152 by ultrasonic welding and contacts the base of the pedestal 136 to clamp the pedestal 136 to the port 152 with the O-ring 140 located 5 therebetween to provide a seal and to isolate the pedestal from unwanted stresses occurring in the transducer 66. In addition, since the clamping action on the pedestal 136 is restricted to its base 158, the upper portion of the pedestal 136, which carries the silicon pressure sensing 10 element 130, is isolated from the stresses associated with the clamping action and from unwanted stresses occurring in the transducer 66.

To join dome 60 to transducer 66, dome 60 is rotated 90 degrees with respect to the position shown in Fig. 2 to 15 bring ears 72, 70 into registry with cut portions 92, 94, respectively of flange 90. Dome 60 is then rotated back toward the position shown in Fig. 2. As that rotation occurs, ears 70, 72 ride up the initial ramp portions of flanges 90, 90' and flanges 90, 90' are received in the spaces between 20 ears 70, 72 and rim 73. As rotation continues, ears 70, 72 ride on the flat portions 98, 98' of flanges 90, 90' until rotation is prevented by contact between ears 70, 72 and the stops 100, 100' on flanges 90, 90'. Finger projections 102 on the periphery of dome housing 62 aid in gripping and 25 rotating dome 60. With dome 60 joined to transducer 66, diaphragms 68 and 118 are in intimate contact, the contact pressure being precisely controlled by the interaction of the

-13-

ears 70, 72, flanges 90, 90' and stop tabs 100, 100'. Contact is further enhanced by the outward bow of diaphragm 118 which is imparted to diaphragm 118 when chamber 142 is sealed. Further, the peripheries of diaphragms 68 and 118 are clamped 5 between rims 124 and 126 to prevent lateral movement of diaphragms 68 and 118. By using a rubber diaphragm 118 with similar mechanical dimensions as rubber diaphragm 68 in disposable dome 60, transducer 66 and dome 60 can be coupled together to facilitate pressure transmission from the dome 60 10 to transducer 66. Since the both diaphragms 68 and 118 are rubber, dome 60 can be uncoupled from and coupled to transducer 66, repetitively, thus providing transducer 66 service for many disposable dome replacement cycles.

The materials used to form the diaphragm 66 and 118 15 must be compatible with the environment in which the pressure sensor is used. Some of the factors in the selection of an appropriate material are compatibility with the oil in chamber 142 and with pressurized IV fluid 12 and compatibility with housing materials and sterilization methods. One 20 rubber material which meets these requirements is nitrile or Buna-n.

Referring now to Figs. 7 and 8, a form of transducer assembly is indicated generally by the reference numeral 210 and includes a fluid inlet port 212 formed with a 25 passageway 214 through which the pressurized fluid or media to be measured enters the transducer 210. The port 212 may be formed from any suitable thermoplastic material having sufficient tensile, shear and compressive strength to with-

-14-

stand exposure to the pressurized fluid. Ports formed from the thermoplastic material sold by the General Electric Company under the designations VALOX 420 and ULTEM 2100 and sold by E.I. DuPont de Nemours and Company under the designation RYNITE 530 were found to be weldable, capable of withstanding a wide range of temperatures (-40°F to 350°F) and compatible with a variety of pressure medias such as acids, organic solvents and automotive and aircraft related fluids.

The port 212 is generally T-shaped in cross-section, 10 with the portion corresponding to the base of the T formed with threads 216 (shown only if Fig. 8) to permit attachment of a fluid supply conduit, not shown. The upper portion 218 of the port 212, which is shown as having a generally rectangular shape but which may be cylindrical or any other 15 suitable shape, is formed with a doughnut shaped recess 220 which is coaxial with passageway 214. A seal in the form of O-ring 222 is located within recess 220 and serves to provide a seal between the the port 212 and a pedestal 224 and to isolate the pedestal 224 from unwanted stresses occurring in 20 the transducer assembly 210, as will be described in detail below. O-ring 222 should be formed of material which is compatible with the pressure media to be tested. For example, a ring formed of neoprene is suitable for use with ammonia and other standard refrigerants. For automotive and related 25 applications involving petroleum based fluids an O-ring formed of nitrile is suitable. Other suitable materials include butyl, silicon, fluorosilicone, etc.

-15-

The pedestal 224 is formed of glass, preferably Pyrex 7740, and includes a cylindrical base portion 226 and an upper generally rectangular sensor supporting portion 228. A passageway 230 extends from the bottom surface of the base 5 portion 226 to the top surface of the sensor supporting portion 228. The pedestal 224 is placed on the O-ring 222 so that the passageway 230 is substantially coaxial with both the opening in the O-ring 222 and the passageway 214 of port 212. As such, pressure media entering the passageway 214 may 10 move through the opening in the O-ring 222 and into passageway 230 of the pedestal 224.

The external diameter of the O-ring 222 and the external diameter of the base 226 of the pedestal 224 are substantially the same. The external diameter of the recess 15 220 formed in the port 212 is slightly larger than that of both the O-ring 222 and base 226. This construction permits the base 226 to be clamped downwardly against the O-ring 222 to create a seal between the port 212 and pedestal 224 so that pressure media will pass without leakage from passageway 214 20 to passageway 230.

A pressure sensing element in the form of a silicon pressure sensing chip 232 having a diaphragm formed on one side thereof is mounted to the sensor supporting portion 228 of the pedestal 224 so that the diaphragm is located over the 25 opening of the passageway 230. In this manner, pressure media comes in contact with the diaphragm of the chip 232, which then generates signals corresponding to the pressure of the media. The chip 232 is secured to the pedestal 224 by anodic

-16-

bonding, the general principles of which are described in detail in U.S. Patent No. 3,397,278. It will be readily appreciated that since the coefficients of thermal expansion of both the glass pedestal 224 and the chip 232 are nearly the 5 same, unwanted stresses due to uneven expansion of the pedestal and chip are eliminated, thereby increasing the accuracy and repeatability of the output of the chip. In addition, the use of the silicon pressure sensing chip 232 and glass pedestal 224 results in excellent corrosion resistance. 10 Further, the large mass and rigidity of the glass pedestal 224 serve to isolate the chip 232 from unwanted bending stresses which would otherwise distort the chip's output.

In order to clamp the pedestal 224 to the port 212 15 with the O-ring 222 therebetween, the transducer assembly 210 of the present invention includes a support member 234 formed with a lower cavity 236 and an upper cavity 238 and a rectangular shaped passage 240 extending therebetween. Specifically, the support member 234 which is preferably formed 20 of the same thermoplastic material as the port 212 and includes a platform 242 in which is formed the passage 240, a downwardly extending wall 244 which forms cavity 236 and an upwardly extending wall 246 which forms cavity 238. In addition, as best seen in Fig. 7 the support member 234 may 25 include structural ribs 248 which provide added strength which may be required in order for the support member 234 to withstand extremely high pressures. Ribs 248 also improve

-17-

dimensional stability by reducing the possibility of the occurrence of large dimensional changes upon cooling of the thermoplastic material after moulding of the support member. Similarly, ribs may also be added to other parts of the 5 support member 234 and other parts of the transducer assembly 210, such as the port 212.

Lower cavity 236 is adapted to receive the upper portion 218 of port 212 and is therefore conformingly shaped. Similarly, passage 240 is adapted to receive the upper 10 rectangular portion 228 of pedestal 224 and is therefore also conformingly shaped. If upper portion 228 is cylindrical in shape, passage 240 should include a keyway to receive a key formed in upper portion 228 so as to prevent its rotation. As best seen in Fig. 8, upper portion 218 of port 212 is 15 received entirely within cavity 236 such that the bottom surface of upper portion 218 is flush with the bottom surface of wall 244. The upper portion 218 is retained within the cavity 236 by ultrasonically welding the two parts together along the outer periphery of the upper portion 218 and the 20 inner periphery of wall 244. A weld depth of from .030 to .050 inches is preferred. It will be appreciated, however, that the top surface of upper portion 218 does not come in contact with the bottom surface of platform 242. This spacing is required to allow the lower surface of the platform 242 25 surrounding the passage 240 to come in contact with the base 226 of the pedestal 224 and clamp the pedestal against the O-ring 222 to effect a seal with the upper portion 218 of the

-18-

port 212. As such, upon welding of the port 212 to the support member 234 the pedestal 224 is clamped against the port 212 by the action of the platform 242 against the base 226 of the pedestal 224. This action compresses the O-ring 222 within 5 the recess 220 to form a seal between the pedestal 224 and port 212 so that pressure media will flow directly from passageway 214 to passageway 230 and in contact with the pressure sensing chip 232. Since the clamping action is restricted to the base 226 of the pedestal 224, the sensor 10 supporting portion 228 of the pedestal, which carries the pressure sensing chip 234, is isolated from the stresses associated with the clamping action.

The sensor supporting portion 228 of the pedestal 224 is located in the passage 240 of the support member 234 and extends into the upper cavity 238 to locate the pressure sensing chip 232 in the upper cavity. Also located in the upper cavity 238 is a conventional circuit board 250, which may be a thick film network, connected to the chip 232 by conventional wire bonds 252. The circuit board 250 carries 20 the circuitry required to standardize the output of the chip 232 and provide temperature compensation. In addition, the circuitry could include signal amplification and an analog to digital converter to provide digital output. A cover 254, shown only in Fig. 1, may be ultrasonically welded over the 25 cavity 238 by using a shear type weld. Pinhole openings may be provided to maintain the pressure of the upper cavity 238 at atmospheric pressure.

-19-

Because of the sealing action of the O-ring 222, the pressure media is restricted to the passageway 214 and 230 and the area between the port 212 and pedestal 224 defined by the O-ring opening. As a result, the structural 5 integrity of the transducer 210 is maintained and no wire bonds or circuit components are exposed to the pressure media which contacts only the one side of the sensing chip 232 on which is formed the diaphragm. In addition to providing a seal between the port 212 and pedestal 224, the 10 O-ring 222 also contributes to the isolation of the pedestal 224 and therefore the sensing chip 232 from unwanted stresses arising in the other parts of the transducer assembly 210. It is theorized that an improvement in stress 15 isolation in high accuracy applications results from the "floating" of the pedestal 224 on the O-ring 222 and the absorption by the O-ring of vibrational energy which would otherwise be transferred to the glass pedestal 224.

It will readily be appreciated that during use of the transducer assembly 210 the only moving part of the 20 transducer is the diaphragm of the sensing chip 232. As a result, the transducer achieves an extremely low volumetric displacement and a corresponding high frequency response. In addition, the transducer assembly 210 is formed from relatively few parts which are secured to each other by only 25 two ultrasonic welds (the port 212 is welded to one end of the support member 234 and the cover 254 is welded to the other end of the support member 234) and, of course, wire

-20-

bonding of the chip 232 to the circuit board 250. As a result of the ease with which the transducer 10 may be assembled and the small number of parts required, the transducer 210 is both inexpensive and well suited to high volume manufacturing processes.

The transducer assembly 210 is also accurate and reliable. Specifically, transducer assembled in the manner described above have been found to have excellent linearity and hysteresis characteristics. Specifically, the transducers were tested by increasing the applied pressure in small increments and recording the output until the pressure limit was reached. The process was then reversed, with the pressure incrementally decreased to zero. This test provided an indication of both linearity and hysteresis (i.e., a comparison of the transducer's operation between an increasing and decreasing pressure). The transducer 210 was also found to have excellent repeatability and offset drift characteristics. Repeatability is the ability of the transducer to maintain the same output after a series of short bursts of pressure cycles between zero and full scale. The offset drift is a measure of the transducers long-term stability and is determined by measuring the null offset at the beginning and end of a given time period.

As will be readily apparent to those skilled in the art, the invention may be used in other specific forms or for other purposes without departing from its spirit or central characteristics. The present embodiments are therefore to

-21-

be considered as illustrative and not restrictive, the scope of the invention being indicated by the claims rather than by the foregoing description, and all embodiments which come within the range of equivalences of the claims are intended 5 to be embraced.

-22-

WHAT IS CLAIMED IS:

1. A transducer for providing an indication of the pressure of a medium comprising a fluid inlet port formed with a passageway permitting flow of fluid through said port, a 5 pedestal having a base and formed with a passageway permitting flow of said fluid through said pedestal, sealing means disposed between said pedestal and said port whereby fluid communication is established between the passageways of said port and said pedestal, a support member secured to 10 said port and including means for contacting said base of said pedestal for clamping said pedestal to said port to maintain the relationship of said pedestal and port with said sealing means located therebetween, and pressure sensing means mounted to said pedestal so that said fluid contacts said 15 pressure sensing means and an indication of the pressure of said medium is provided.

2. Apparatus as in Claim 1 in which said port is formed with a recess adapted to receive said sealing means.

3. Apparatus as in Claim 1 in which said sealing 20 means comprises an O-ring.

4. Apparatus as in Claim 1 in which said port and said support member are formed of thermoplastic material and are secured to each other by ultrasonic welding.

5. Apparatus as in Claim 1 in which said support 25 member is formed with an opening which permits passage of all of said pedestal except said base, means for securing said port to said support member so that the portion of said

-23-

support member adjacent said opening contacts said base and clamps said pedestal to said port with said sealing means located therebetween.

6. A sensor for use in a biomedical pressure measuring and monitoring system comprising a dome including a dome chamber having at least one opening therein, first diaphragm support means defining said at least one opening, a flexible non-metal dome diaphragm mounted on said first diaphragm support means and sealing said at least one opening 10 of said dome chamber, and a transducer including a housing having a transducer chamber with at least one opening therein, second diaphragm support means defining said at least one opening, pressure responsive elements mounted in said transducer chamber, a flexible non-metal transducer diaphragm 15 mounted on said second diaphragm support means and sealing said at least one opening in said transducer chamber, a relatively high viscosity fluid filling said chamber between said transducer diaphragm and said pressure responsive elements, said fluid transmitting a force exerted on said 20 transducer diaphragm to said pressure responsive elements, said dome and said transducer being coupled together so that said first and second diaphragm support means cooperate to clamp the dome diaphragm and the transducer diaphragm together along their peripheries, whereby the dome diaphragm 25 contacts the transducer diaphragm to permit pressure on said dome diaphragm to be transmitted to the transducer diaphragm and to said pressure responsive elements and whereby lateral

-24-

movement of said diaphragms is restrained, said pressure responsive elements providing an output signal indicative of the pressure.

7. A sensor for use in a blood pressure monitoring system including a pressurized fluid and means for conveying the pressurized fluid into the blood stream of a patient, said sensor comprising a dome including a dome chamber having at least one opening therein and adapted to receive said pressurized fluid, first diaphragm support means defining said at least one opening and a rubber dome diaphragm mounted on said first diaphragm support means and sealing said at least one opening of said dome chamber, and a transducer including a housing having a transducer chamber with at least one opening therein, second diaphragm support means defining said at least one opening, pressure responsive elements mounted in said transducer chamber, a rubber transducer diaphragm mounted on said second diaphragm support means and sealing said at least one opening in said transducer chamber, a relatively high viscosity fluid filling said chamber between said transducer diaphragm and said pressure responsive elements, said fluid transmitting a force exerted on said diaphragm to said pressure responsive elements, said dome and said transducer being coupled together so that said first and second diaphragm support means cooperate to clamp the dome diaphragm and the transducer diaphragm together along their peripheries, whereby the dome diaphragm contacts the transducer diaphragm to permit pressure of the pressurized fluid to be transmitted from the dome diaphragm to the transducer

-25-

diaphragm and to said pressure responsive elements and whereby lateral movement of said diaphragms is restrained, said pressure responsive elements providing an output signal indicative of the pressure of said pressurized fluid to 5 thereby provide an indication of a patient's blood pressure.

8. The sensor of Claim 7, wherein said transducer further includes all ball means sealing a second opening in said transducer chamber to ensure that said fluid completely fills said transducer chamber and causes said transducer 10 diaphragm to bow outwardly toward said dome diaphragm.

9. A sensor for use in a biomedical pressure monitoring system comprising:

a transducer housing having a circular opening therein,

15 a circular slot in said housing surrounding said opening and creating a circular clamping rim surrounding said opening,

a rubber diaphragm covering said opening and having an annular rim disposed in said circular slot,

20 a pressure responsive device in said housing and spaced from said diaphragm,

a dielectric oil filling said housing and forming a medium for transmitting movement of said diaphragm to said pressure responsive device,

25 a dome having a circular opening therein and ports for the passage of a fluid whose pressure is monitored,

a circular slot around said circular dome opening

-26-

and creating a circular clamping rim of substantially the same diameter as said housing clamping rim,

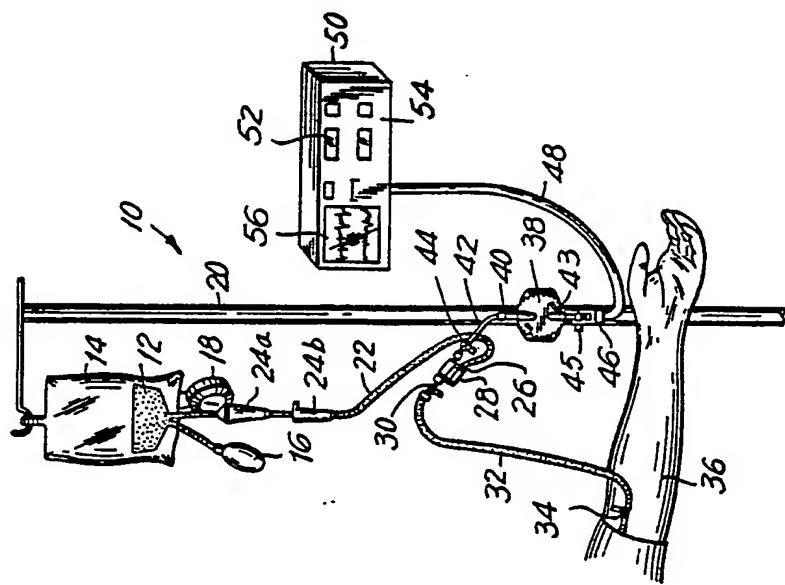
a rubber diaphragm covering said dome opening and having a rim disposed in said circular dome slot,

5 and means for removably mounting said dome on said housing with said diaphragms clamped together between said clamping rims.

10. A sensor as in Claim 9 wherein said diaphragm rims disposed in said circular slots provide O-ring type 10 seals to prevent leakage of liquids out of the openings in said housing and dome respectively.

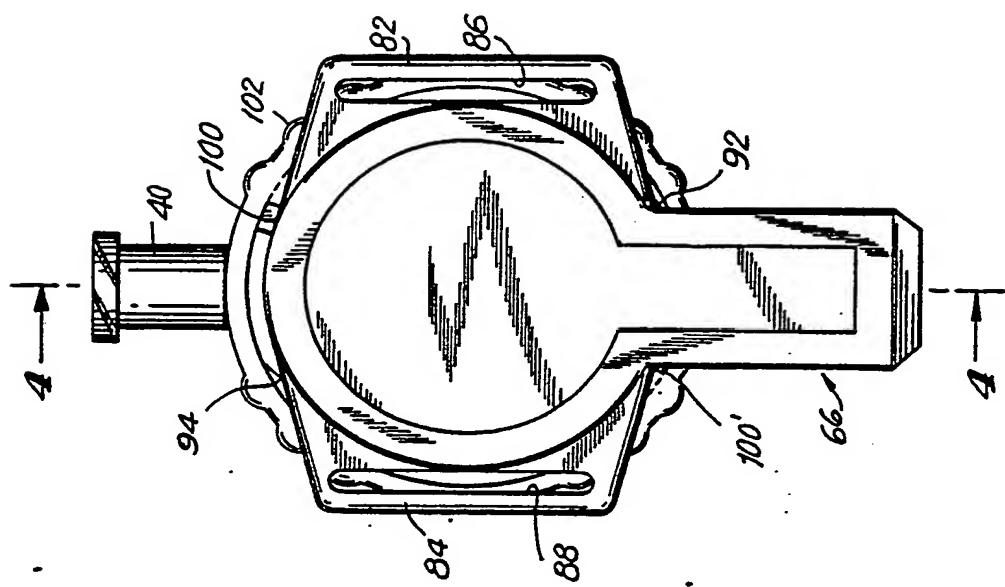
1/5

FIG. 1

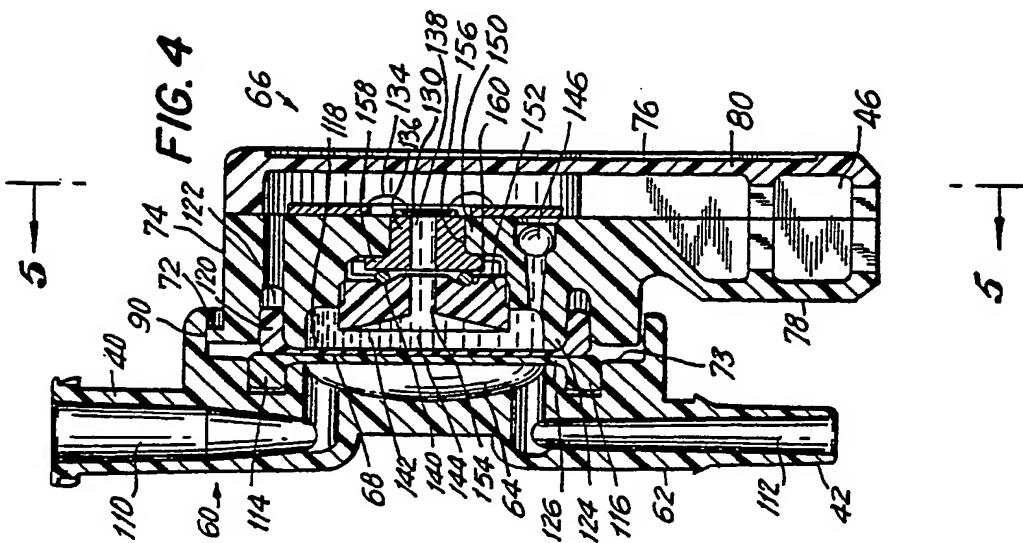


2/5

FIG. 3



4



3/5

FIG. 5

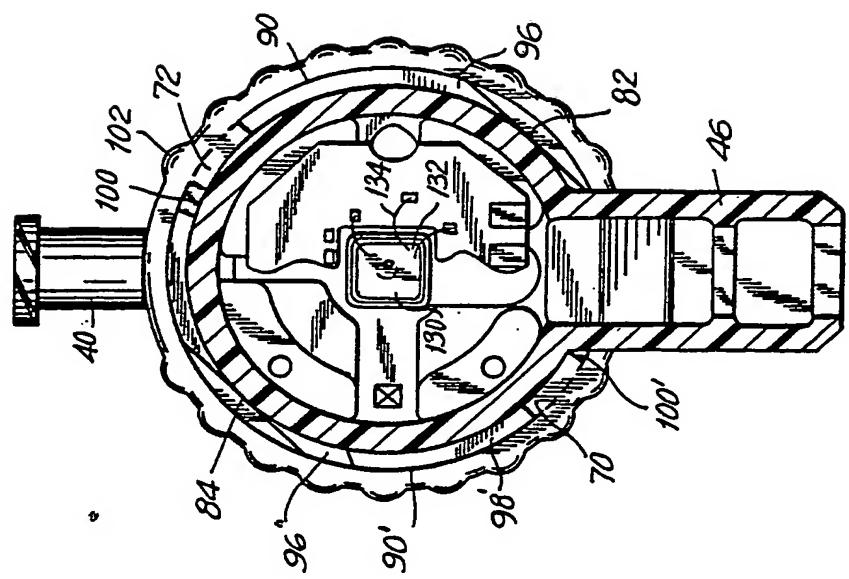
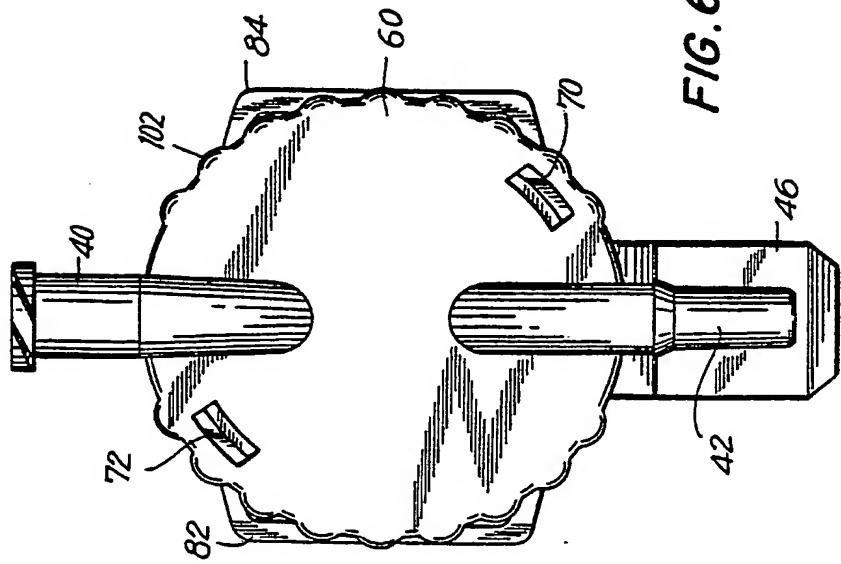


FIG. 6



4/5

FIG. 7.

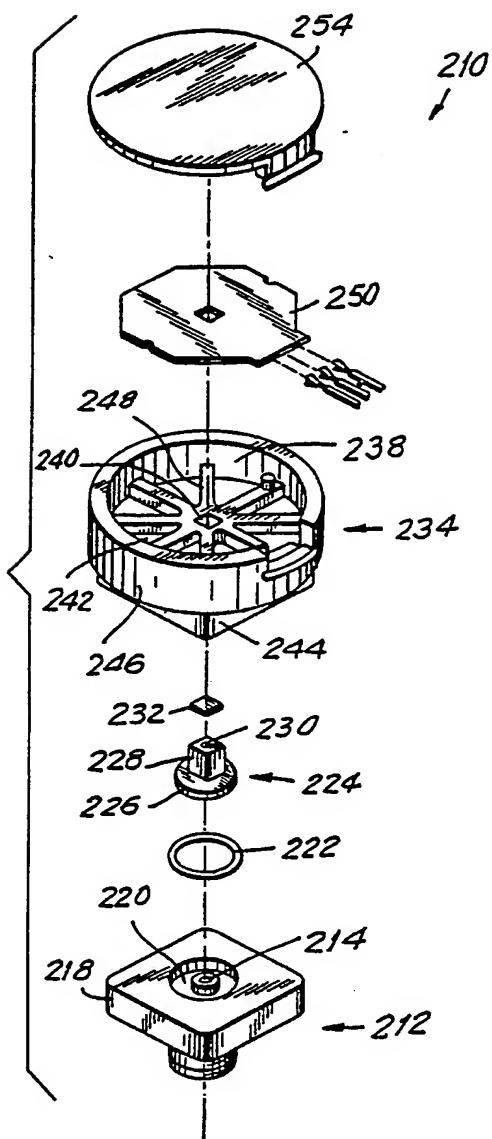
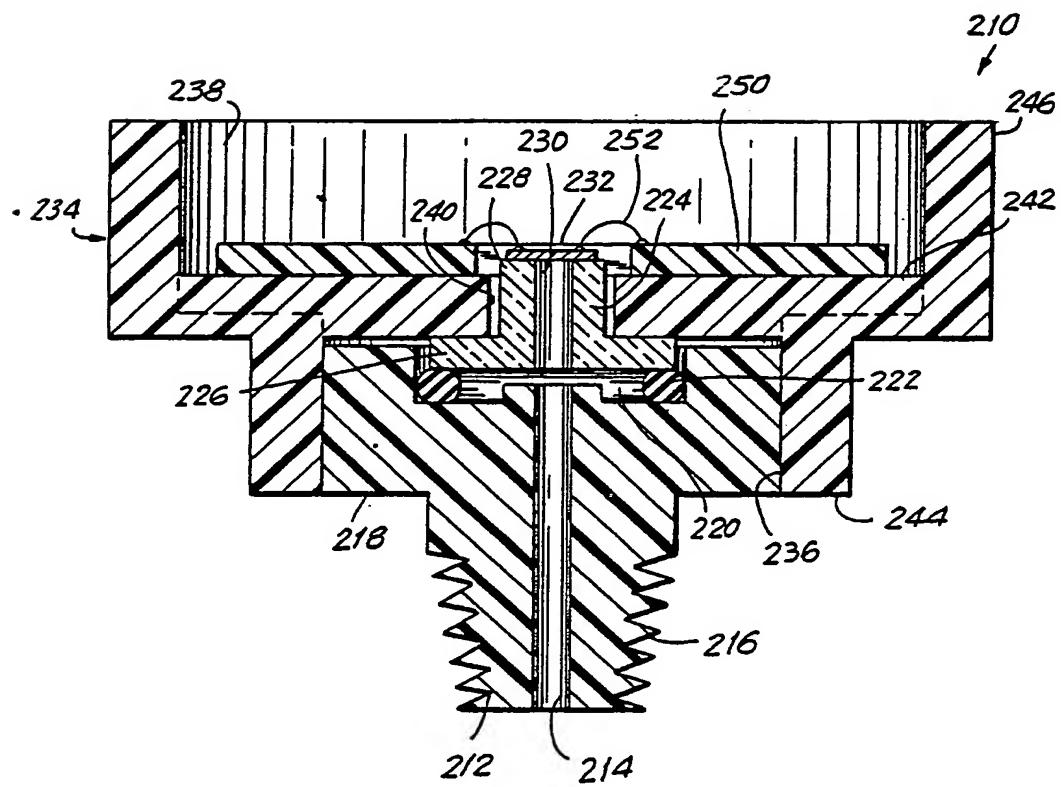


FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 85/01957

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC⁴ : G 01 L 9/06; A 61 B 5/02

II. FIELDS SEARCHED

Minimum Documentation Searched ⁷

| Classification System | Classification Symbols |
|-----------------------|------------------------|
| IPC ⁴ | G 01 L 9 |
| | G 01 L 7 |
| | G 01 L 19 A 61 B 5 |

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT*

| Category * | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ |
|------------|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| X | Electronic Engineering, volume 53, no. 659, November 1981, London, (GB) E. Bose: "Fluid pressure transducers", page 169, see figure 1 | 1-3, 5 6-10 |
| Y | -- | |
| Y | US, A, 4127840 (J. HARDY HOUSE) 28 November 1978, see column 5, lines 52-68; figure 1 | 1, 2 |
| Y | -- | |
| Y | US, A, 4252126 (J.P. MANDL) 24 February 1981, see column 2, lines 39-68; column 3, lines 1-43; figures | 6, 7 |
| Y | -- | |
| Y | WO, A, 82/01997 (IVAC CORPORATION) 24 June 1982, see page 5, lines 8-32; page 6, lines 1-14; page 7, lines 26-29; figure 7 | 6, 7 |
| Y | -- | |
| Y | US, A, 4072056 (A. ST. J. LEE) 7 February 1978, see abstract; figure 1 | 6, 7 |
| Y | -- | |
| Y | FR, A, 1087783 (ALLTOOLS LTD. et al.) 28 February 1955, see page 2, left-hand | 6, 7, 9, 10 . / . |

* Special categories of cited documents: ¹⁰

"A" document defining the general state of the art which is not considered to be of particular relevance .
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

13th March 1986

Date of Mailing of this International Search Report

10 APR 1986

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

M. VAN MOL

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

| | | |
|---|-----------------------------------------------------------------------------------------------|-----|
| | column, sections 1 and 2; figure 4 -- | |
| Y | DE, C, 888933 (H.C. ULRICH) 7 September 1953, see page 2, lines 20-60; figures -- | 6,7 |
| Y | US, A, 3559488 (J.A. WEAVER) 2 February 1971, see column 2, lines 53-63; figure 1 ----- | 8 |

V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This International search report has not been established in respect of certain claims under Article 17(2) (e) for the following reasons:

1. Claim numbers because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this international application as follows:

- claims 1-5 : Pressure transducer; mounting of pedestal on sealing means
- claims 6-10 : Biomedical pressure sensor; arrangement of 2 contacting diaphragms for transmitting pressure

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/US 85/01957 (SA 11046)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 02/04/86

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|----------------------------------------|------------------|-------------------------------------------------|----------------------------------|
| US-A- 4127840 | 28/11/78 | None | |
| US-A- 4252126 | 24/02/81 | None | |
| WO-A- 8201997 | 24/06/82 | EP-A- 0066613 US-A- 4398542 CA-A- 1167342 | 15/12/82 16/08/83 15/05/84 |
| US-A- 4072056 | 07/02/78 | None | |
| FR-A- 1087783 | | None | |
| DE-C- 888933 | | None | |
| US-A- 3559488 | 02/02/71 | DE-A- 2040786 FR-A- 2058951 GB-A- 1263039 | 25/02/71 28/05/71 09/02/72 |